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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,937	09/30/2002	Geoffrey H. White	VAS-5511A	4752

30452 7590 03/29/2004

EDWARDS LIFESCIENCES CORPORATION
ONE EDWARDS WAY
IRVINE, CA 92614

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

9

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,937

Applicant(s)

WHITE ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4.8.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 9/23/99. It is noted, however, that applicant has not filed a certified copy of the Australia PQ 3029 application as required by 35 U.S.C. 119(b).

Drawings

2. Figures 2, 4 and 6 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference number "27" in Figure 1 is not mentioned in the specification. It appears that "27" should be changed to --21-- for graft end. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because it appears that "17" in Figure 3 should be changed to --22-- to indicate a tube rather than the renal artery. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Specification

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
6. The disclosure is objected to because of the following informalities: on page 11, lines 1-2, the sentence beginning "The graft 10..." is identical to the previous sentence and therefore, should be deleted. Appropriate correction is required.

Claim Objections

7. Claims 1 and 20 are objected to because of the following informalities:
- a) In claim 1, line 2, a comma should be inserted after "length".
 - b) In claim 19, line 4, "that" should be changed to --than--.
 - c) In claim 20, line 1, "according" should be deleted.
- Appropriate correction is required.
8. Claim 9 is objected to because it is identical to claim 8, and therefore does not further limit the claimed invention. The examiner suggests canceling claim 8.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 5-7 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 5, 6, and 7 require that the tubular body further comprise two, three and four pieces, respectively. These claims are indefinite because it is unclear, in light of the specification, what the "pieces" are referring to. What are the pieces of? Is applicant referring to stents or wire reinforcements? If so, the specification does not support that the tubular body comprise the specific number of pieces.

11. Claim 20 recites the limitation "other delivery device" in lines 7 and 9 and "device body" on line 3. There is insufficient antecedent basis for these limitations in the claims. It appears that --or other delivery device-- should be inserted in lines 3 and 5 after "catheter".

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nunez et al. (USPN 5,800,514).

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Nunez et al. discloses an intraluminal device with all the elements of claim 1. See Figure 6 and column 3, lines 58-63 for a tubular body having a length, a first end, and at least one second end wherein the tubular body is being of a pre-determined non-linear shape.

Claims 2-4, see Figure 6 and column 8, lines 56-67 for a sigmoid curve along the length of the tubular body between the first and at least one second end.

Claims 5-7, see column 1, lines 37-45 and column 16, lines 14-17 for the tubular body further comprising several stents, which provide as the “pieces”.

Claims 8 and 9, see column 3, line 55 for the tubular body being a graft, which is structurally capable of bridging an aneurysm in an artery of a patient to meet the intended use limitation.

With respect to claims 10-12, “in an anterior-posterior plane” and “in a lateral plane” relate to the device when it is implanted into the body. Because the tubular body of the intraluminal device is matching the diameter and shape of the vessel it is being implanted into, it is inherent that the body will have curvature along its length in these planes.

Claims 13 and 14 are product-by-process claims, and according to MPEP § 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. The tubular body is curved along the length between the first and at least one second end, and therefore meets the structural limitations of the claims. In addition, see column 2, lines 55-57 for it being old and well known in the art to use cutting in forming desired sized and shaped grafts.

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With respect to claims 17 and 18, the limitations of determining the shape of the vessel or vessel portion and determining is by ultrasound, plain abdominal films and CT scanning, do not further structurally limit the claimed invention of an intraluminal device.

14. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (USPN 5,800,520).

Fogarty et al. discloses an intraluminal device with all the elements of claim 19. See Figure 11 and column 9, lines 40-54 for a tubular graft body (30) having a length, a first end and at least one second end wherein the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater than the remainder of the first end.

15. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Khan et al. (USPN 5,928,258)

Khan et al. discloses a method for emplacing an intraluminal device with all the elements of claim 20. See column 1, lines 21-30 for disclosure of the state of the art including introducing a delivery device (sheath) into an artery of a patient with the device body (stent-graft) is in a radially compressed state; causing the device (stent-graft) to be moved through the delivery device (sheath) until the device (stent-graft) extends into the vessel from a proximal end of the delivery device (via plunger catheter); and allowing the device (stent-graft) to expand. The examiner contends that once delivery and deployment of the device is complete, it is inherent that the delivery device will be withdrawn.

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Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

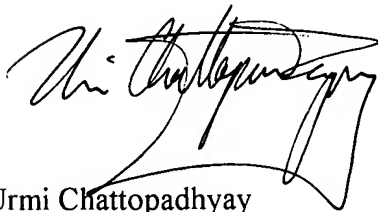
17. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nunez et al. in view of Fogarty et al.

Nunez et al. discloses an intraluminal device with all the elements of claim 1, but is silent to the first end of the tubular body being angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater than the remainder of the first end, as required by claims 15 and 16. Fogarty et al. teaches an intraluminal device wherein a first end is angled as required in order to reduce restenosis. See Figure 11, column 1, lines 10-14 and column 9, lines 40-54. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Fogarty et al. to modify the intraluminal device of Nunez et al. by making the first end of the tubular body angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater than the remainder of the first end in order to reduce restenosis.

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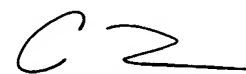
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700